DERWENT-ACC-NO: 1994-034699

DERWENT-WEEK: 199639

TITLE: Fitting for in-vitro testing of circumferentially compliant prosthetic valve - places valve in simulated aorta supported at ends by rings with fluid seals

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PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC	
WO 9401061 A1	January 20, 1994	E	031	A61F 002/24	
US 5546820 A	August 20, 1996	N/A	017	G01M 010/00	
AU 9346593 A	January 31, 1994	N/A	000	A61F 002/24	
US 5406857 A	April 18, 1995	N/A	019	G01M 019/00	

CITED-DOCUMENTS: US 4682491; US 5139515 ; WO 8901765 ; WO 9219199 ; WO 9304643

APPLICATION-DATA:

PUB-NO	APPL-DESCRIPTOR	APPL-NO	APPL-DATE
WO 9401061A1	N/A		
1993WO-US06242			June 30, 1993
US 5546820A	Cont of		
1992US-0910933			July 9, 1992
US 5546820A	N/A		
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AU 9346593A	N/A	
1993AU-0046593	June 30, 1993	
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INT-CL (IPC): A61F002/24, F16K037/00 , G01M010/00 , G01M019/00

ABSTRACTED-PUB-NO: US 5406857A

BASIC-ABSTRACT:

A fitting for in-vitro testing of a circumferentially compliant prosthetic valve comprises a cradle (22) to support the ends of a simulated human aorta (10) which can receive a valve so that a flow simulating natural blood flow can be passed through aorta and valve. There is a fluid seal at each end so that the fixture can be installed in a sealed flow loop of testing appts..

The aorta is pref. made of compression-moulded silicone rubber, and the valve is non-stented. The aorta ends are pref. folded back over cylindrical rims of respective **adapter** rings which carry the seals and can fit into appts. **receivers**. USE/ADVANTAGE - Used partic. for testing non-stented valves. The fitting facilitates testing and allows reliable results to be obtd. in a manner which takes account of the effects of valve compliance.

ABSTRACTED-PUB-NO: US 5546820A

EQUIVALENT-ABSTRACTS:

A fixture for in vitro testing of a circumferentially compliant biophosthetic valve comprises a simulated aorta patterned from dimensions of a natural human

aorta having a hollow cylindrical shape with open inflow and outflow ends with
a set circumferential compliance and adapted to receive the valve; an inflow
end **adapter** annular ring disposed around its inner circumference such that the
aorta inflow end is received and supported to permit flow simulating natural
blood flow through aorta and valve with the inflow end folded back over the rim
on the ring; an outflow annular **adapter** ring with cylindrical rim around its
inner circumference such that the outflow end of the aorta is received and
support to permit flow simulating natural blood flow through the aorta and
valve. The aorta outflow end is folded back over the cylindrical rim on the
outflow end **adapter** ring, the rings having fluid seals allowing them to be
received in receptacles in a testing appts. such that the aorta is disposed
along a sealed test flow loop of the fixture.

ADVANTAGE - A single in vitro test is all that is required.

A fixture for in-vitro testing of a circumferentially compliant bioprosthetic
valve, comprising: a simulated aorta patterned from dimensions of a natural
human aorta, having a generally hollow cylindrical shape with open inflow and
outflow ends, the aorta having a predetermined circumferential compliance, and
the aorta adapted to receive the circumferentially compliant bioprosthetic
valve in a desired spatial relationship; a test fixture cradle, adapted to
receive and support the ends of the simulated aorta and valve to permit flow
simulating natural blood flow through the aorta and valve and to prevent
interference with the compliance characteristics of the aorta and valve; and
said test fixture cradle further having fluid seals disposed on each end of it,
allowing the test fixture to be installed in a sealed flow loop of a testing

appts. and the aorta and valve to be disposed along the sealed flow loop of the
appts.

WO 9401061A

CHOSEN-DRAWING: Dwg.9/13 Dwg.0/13 Dwg.7/13

TITLE-TERMS: FIT VITRO TEST CIRCUMFERENCE COMPLIANT **PROSTHESIS** VALVE PLACE
VALVE SIMULATE AORTA SUPPORT END RING FLUID SEAL

DERWENT-CLASS: A96 D22 P32 Q66

CPI-CODES: A06-A00E3; A12-L; A12-V02; D09-C01B;

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See image for Certificate of Correction

TITLE: Driver tool for **heart valve** prosthesis fasteners

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A driver tool which drives helical fasteners through a **heart valve** component into tissue. The tool has a tool housing with a distal end couplable to engage the implanted component. A drive shaft at the proximal end of the driver tool couples to a driving force. Multiple driver tips couple to helical fasteners for the **heart valve** component. A drive train in the tool housing distributes the drive to the driver tips.

Driver tool for **heart valve** prosthesis fasteners

This application is a continuation-in-part of application serial number 09/062,822, filed Apr. 20, 1998 and titled "TWO PIECE PROSTHETIC **HEART VALVE.**"

The present invention relates to mechanical **heart valve** prostheses. More specifically, the invention relates to a driver tool for attaching and implanting **heart valve** prostheses.

Implantable mechanical **heart valves** are used for replacement of defective valves in hearts of patients. One common method employs a sewing ring or suture cuff which is attached to and extends around the outer circumference of the mechanical valve orifice. The sewing cuff is made of a biocompatible fabric suitable for allowing a needle and suture to pass

therethrough. The valves are typically sutured to a tissue annulus that is left when the surgeon removes the existing valve from the patient's heart. The sutures are tied snugly, thereby securing the valve to the heart.

Another technique for attaching heart valves uses a series of pins which pierce the tissue annulus of the heart. The pins are crimped or bent, thereby locking the valve to the heart tissue and preventing the valve from separating from the heart. This technique is described in U.S. Pat. Nos. 3,574,865 and 3,546,710. Another technique for attaching a prosthetic heart valve to the heart tissue is shown in U.S. Pat. No. 4,705,516 in which an outer orifice ring is sutured to the tissue annulus and an inner orifice ring is then screwed into the outer orifice ring. However, the rings are not locked together and may become unscrewed after extended use.

Implantable heart valves can require fasteners to hold them securely to surrounding tissue in the body. Suturing has been used. However, the use of suturing is time consuming and increases the duration of the implantation surgical procedure. The use of helical fasteners or screws is disclosed in the above cited pending application. However, access one at a time to the multiple helical fasteners used with an implant can be difficult and time consuming. The fasteners face in different directions and a simple tool must be positioned multiple times to approach the implantable heart valve component from several difficult angles around the heart, some of which may be obstructed by adjoining tissue. There is a

need for an improved technology for screwing helical fasteners through a heart valve component into a tissue annulus of the heart.

The present invention is useful in implanting a prosthetic **heart valve** in a heart with helical fasteners. The **heart valve** includes an outer ring for coupling to a tissue annulus of a heart. An inner orifice ring includes an occluding mechanism movable between an open position, which allows blood flow through the lumen, and a closed position which prevents blood flow through the lumen. The inner orifice ring is adapted to be coupled to the outer orifice ring after the outer orifice ring has been attached to the tissue annulus. The outer ring is attached to the tissue annulus by helical screws and is coupled to the inner orifice ring by a snap fit.

In the present invention, a driver tool drives multiple helical fasteners simultaneously through the outer ring of a **heart valve** component into the surrounding tissue annulus of a heart. The driver tool includes a tool housing and has a distal end couplable to engage the **heart valve** component and a proximal end spaced from the distal end. A drive shaft at the proximal end is couplable to a driving force. A plurality of driver tips extend from the distal end, each driver tip coupling to a helical fastener for the **heart valve**. A drive train in the tool housing couples to the drive shaft to distribute driving force to each of the driver tips.

FIG. 1 is an exploded cross-sectional view of a prosthetic **heart valve**.

FIG. 2 is a cross-sectional view of the **heart valve** of FIG. 1.

FIG. 3 is a perspective view of an attachment mechanism for the prosthetic **heart valve** of FIGS. 1 and 2.

FIG. 4 is a side cross-sectional view of an implantation

tool for implanting
the heart valve prosthesis shown in FIGS. 1 and 2.

FIG. 9 is a perspective view of a holder for use in implanting an outer ring
of a heart valve.

FIG. 10 is a side cross sectional view of a driver tool engaging a heart
valve outer ring and coupled to helical fasteners in accordance with the
present invention.

FIG. 11 is a side cross sectional view of a driver tool engaging a heart
valve outer ring and coupled to helical fasteners in accordance with the
present invention.

Heart valve prosthesis 10 shown in FIG. 1 includes inner orifice ring 12 and
outer orifice ring 14. FIG. 1 is a side cross-sectional exploded view of valve
10 and FIG. 2 is a side assembled cross-sectional view of valve 10.

Inner orifice ring 12 includes locking recess 16 (or, in another embodiment,
a ridge) formed around its outer circumference. Leaflets (or occluders) 18
provide an occluding mechanism and are pivotably coupled to ring 12 at pivot
guard 20. Leaflets or occluders 18 move between an open position (not shown)
and a closed position as shown in FIGS. 1 and 2 in which flow of fluid through
lumen 22 is blocked. Leaflets 18 rotate within pivots 24 formed in pivot
guards 20. In one preferred embodiment, inner ring 12 comprises a prosthetic
heart valve available from St. Jude Medical, Inc. of St. Paul, Minn.
without a sewing cuff carried thereon. However, in some embodiments it may be
preferable to use a specially designed inner ring 12.

FIG. 4 is a side cross-sectional view of tool 60 for use in snapping inner

ring 12 into outer ring 14 of heart valve prosthesis 10 shown in FIGS. 1 and 2.
Tool 60 includes elongated handle 62 including proximal gripping end 64.
Actuator rod 66 extends through a center opening 68 in handle 62. Holder 70 is
coupled to a distal end of handle 62. Holder 70 includes moveable half 72A and
fixed half 72B coupled at pivot 74. Halves 72 include lower lip 76 adapted to
abut outer ring 14. Distal end 80 of actuator rod 66 couples to actuator cable
82 which is connected to half 72A. Spring 84 is coupled to actuator rod 66 and
pushes actuator rod 66 in an axial direction away from holder 70 holding halves
72 in the closed position as shown in FIG. 4. Rod 66 includes actuator button
90. Proximal end 64 of handle 62 includes handle grip 93.

Orifice pushing mechanism 91 is aligned axially with handle 62 and coupled
to handle 62 by threads 92. Mechanism 91 includes gripping portion 94 and
orifice abutting surface 96. As shown in FIG. 4, orifice abutting surface 96
is adapted to abut inner orifice ring 12.

FIG. 5 is a side cross-sectional view of a portion of tool 60 showing holder
70 in an open position in which half 72A is rotated about pivot 74. In this
position, heart valve prosthesis 10 is freed from holder 70 such that heart
valve prosthesis may be selectively removed from, or engaged with holder 70.

Ring 100 is sutured to tissue annulus 42 using sutures 106 which extend
radially through cuff 102 and suture holes 104. Preferably, sutures 106 are
metal sutures of a biocompatible material such as stainless steel. After the
sutures 106 are threaded through the patient's natural tissue annulus and outer
orifice ring 100, the surgeon secures the suture using knots 114 which may be
formed by twisting the suture 106 as shown in FIG. 6.

Excess suture material is then trimmed and knots 114 are folded into suture grooves 108.

FIG. 9 is a perspective view of implantation tool 150 for use in implanting orifice ring 100. Tool 150 includes legs 152 having coupling tips 154 which are configured to couple to ring 100. Tool 150 may be used by the surgeon to hold ring 100 during suturing such that force may be applied to ring 100. Tips 154 may be fit into suturing grooves 108. Tool 150 includes handle attachment opening 156 which may be used to selectively engage an elongated handle (not shown). Opening 156 can be as shown or can be a **threaded** hole, a snap fit hole or other opening adapted to selectively engage an elongated handle.

In FIG. 10, driver tool 210 is shown engaging outer ring 212 of a two piece prosthetic **heart valve**. Driver tool 210 couples to helical screw fasteners 214 which pass through holes in outer ring 212. Helical fasteners 214 can be any fastener that advances along its central axis by being turned about that axis, i.e., anything that goes in by twisting, such as a screw. Helical screw fasteners 214 attach outer ring 212 to tissue annulus 213 during an implantation procedure using driver tool 210. Driver tool 210 includes tool housing 216, which is generally cylindrical in shape, or round in cross section, and extends from distal end 218, which engages outer ring 212, to proximal end 220 spaced away from the distal end 218. Drive shaft 222 at proximal end 220 has a handle 224 that can receive a twisting or driving force for transmission to helical screw fasteners 214. Handle 224 can also be actuated or pulled away from the proximal end 220 to disengage driver tool 210 from helical screw fasteners 214.

The tissue annulus of the heart has been prepared to receive the **heart valve** prosthesis pursuant to techniques known in the art. Driver tool 210 has been preloaded with outer ring 212 snapped on its distal end 218 and helical screw fasteners 214 inserted in outer ring 212 and coupled to driver tips 266. Distal end 218 is then advanced toward prepared tissue annulus 213 until outer ring 212 is aligned within the tissue annulus. Handle 224 is twisted to advance helical screw fasteners 214 into the tissue annulus. When outer ring 212 is attached by helical screw fasteners 214 to the tissue annulus, handle 224 is lifted relative to tool housing 216. This compresses spring 272 and disengages driver tips 266 from helical screw fasteners 214 if they have not already been disengaged by the advance of the helical fasteners. Handles 226 and 228 are squeezed together, unsnapping outer ring 212 of the **heart valve** from the tool 210. The tool 210 is removed, leaving outer ring 212 attached to the tissue annulus of the heart by multiple helical fasteners.

Preferably, the rings set forth herein are formed of biocompatible materials. The outer ring is generally made of material more flexible than the inner ring, such as polyethylene terephthlate (PET), polyetheretherketones (PEEK), ultrahigh molecular weight polyethylene, Nitinol.RTM. (a nickel-titanium alloy), and polyurethane. The inner ring is made preferably of a material more rigid than the outer ring such as titanium, MP35N (wrought cobalt-nickel-chromium-molybdenum alloy), ceramic, Elgiloy.RTM. (cobalt-chromium-nickel-molybdenum iron alloy), pyroltic carbon or other rigid polymers for the inner ring. The particular shapes of the orifice rings and

attachment mechanisms may be modified as appropriate. The ring coupling mechanism for coupling the two rings may be any mechanism as desired and is not limited to the particular "snap" coupling techniques set forth herein. For example, the coupling techniques may include screws, wires, bayonet locking mechanism, and nails which extend axially and engage the rings. Further, the configuration of the inner orifice ring and its occluding mechanism may be other than those set forth herein.

1. A driver tool for a heart valve prosthesis component for driving helical fasteners through the heart valve prosthesis component into a tissue annulus of the heart, comprising:

a tool housing having a distal end couplable to engage the heart valve prosthesis component and a proximal end spaced away from the distal end; and

a drive train mounted in the tool housing having a drive shaft at the proximal end couplable to a driving force and a plurality of driver tips at the distal end couplable to the helical fasteners in the heart valve prosthesis component, the drive train distributing the driving force to each of the driver tips.

a decoupling mechanism in the tool housing receiving the second actuation motion and decoupling the driver tool from the heart valve prosthesis component responsive to the second actuation motion.

13. A driver tool for driving helical fasteners through a heart valve component into tissue, comprising:

a tool housing having a distal end couplable to engage the heart valve

component and a proximal end spaced away from the distal end;

a plurality of driver tips extending from the distal end, each driver tip couplable to a helical fastener for the **heart valve** component; and

14. A method of attaching an outer ring of a **heart valve** prosthesis component into a tissue annulus of a heart with helical fasteners, comprising:

attaching the outer ring of the **heart valve** prosthesis component to the distal end;

placing the multiple helical fasteners on the multiple driver tips and passing them through the outer ring of the **heart valve** prosthesis component;

15. A kit for attaching a **heart valve** prosthesis component to an annulus of tissue in a heart, comprising:

an outer ring of a **heart valve** prosthesis component;

a driver tool having a handle extending from a drive shaft on a proximal end and distributing drive to a plurality of driver tips on a distal end of the driver tool, the distal end being removably attached to the outer ring of the **heart valve** prosthesis; and

a plurality of helical fasteners passing through the outer ring of the **heart valve** prosthesis, each one of the helical fasteners removably coupling to one of the plurality of driver tips.

	Type	L #	Hits	Search Text	DBs	Time Stamp
1	BRS	L1	201	adapter and receiver and (implant or organ)	USPAT; EPO; JPO; DERWENT	2003/04/15 10:25
2	BRS	L2	82	adapter and receiver and (implant or prosthesis)	USPAT; EPO; JPO; DERWENT	2003/04/15 10:31
3	IS&R	L3	39	(623/2.38).CCLS.	USPAT	2003/04/15 10:32
4	IS&R	L4	39	(623/2.38).CCLS.	USPAT	2003/04/15 10:38
5	IS&R	L23	115	(623/2.11).CCLS.	USPAT	2003/04/15 10:43
6	BRS	L24	12	623/2.11.ccls. and cells	USPAT	2003/04/15 10:44
7	BRS	L26	56	heart adj3 valve$ and cover$ adj7 (cell or cells)	USPAT	2003/04/15 10:46

	Comments	Error Definition	Errors
1			0
2			0
3			0
4			0
5			0
6			0
7		Truncation overflow.	1